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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/529,967	04/24/2000	MATTI KORPELA	2328-117	8859

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/29/2002

#17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/529,967	Applicant(s) KORPELA ET AL.	
	Examiner Bradley L. Sisson	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *11-15 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 April 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634, and has been assigned to Primary Examiner Bradley L. Sisson.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 February 2002 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-10 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In evaluating whether an application has satisfied the

written description requirement under 35 USC 11, first paragraph, the question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, an application, must describe the invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention. *Lockwood v. American Airlines Inc.* (Fed. Cir.) 41 USPQ2df 1961, at 1966. Here, applicant is seeking patent protection for a generic claim of determining tetracycline using any cells and constructs that have been defined functionally. While generic protection is possible, such broad scope of protection, however, also requires greater levels of disclosure. Guidance for just what level of showing is considered to meet this requirement can be found in the *University of California v. Eli Lilly and Co.* (FED. Cir. 1997) 43 USPQ2d 1398, 1406, citing *In re Angstadt*, 537 F. 2d 498, 190 USPQ 214 (CCPA 1976) that a "disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process." Here, claims are drawn to a generic method using nucleic acid sequences that are defined not in terms of what they are but in terms of how they are to function; *Lilly*. In claim 10 it is seen that the claims are directed to the testing of specific products. A review of the disclosure, however, fails to locate where applicant has adequately described the testing or analysis of these products. Similarly, the claimed method encompasses the use of virtually any recombinant prokaryotic cell that has comprises a DNA vector comprises a gene that encodes a light-producing enzyme. A review of the disclosure, however, finds but a single construct and but a single type of cell. While one may argue that other such cells and constructs are obvious, obviousness of claimed yet non-disclosed embodiments does not satisfy the written description requirement; *Angstadt*.

5. Claims 1-10 and 16-19 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of *E. coli* K-12/pTetLux1 and *E. coli* K-12/TetLuc1 to detect the presence of tetracycline in the presence of culture broth as well as in spiked limpec porcine serum, does not reasonably provide enablement for the detection of any and all levels of tetracycline in any type of sample, regardless of its heterogeneity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Quantity of Experimentation Necessary

The quantity of experimentation need is great, on the order of several man-years and then with little, if any, reasonable expectation of success.

The Amount of Direction or Guidance Provided and The Presence or Absence of Working Examples

The specification provides five examples:

Example 1, page 16, reconstitution of freeze-dried *E. coli* K-12/pTetLux1;

Example 2, page 17, construction of different sensors;

Example 3, page 18, measurement of tetracycline levels in pig serum;

Example 4, page 18, measurement of tetracycline in milk using the chelator EDTA; and

Example 5, page 18, provides a description of Figure 11 as it relates to "the kinetics of bacterial bioluminescence after exposure of *E. coli* K-12/pTetLux1 to different dilutions of tetracycline antibiotics."

In Example 2, page 17 of the specification, a comparison was conducted between *E. coli* K-12/pTetLux1 and *E. coli* K-12/TetLuc1. In Example 3, (page 18, first paragraph) "fresh *E. coli* K-12/pTetLux1 were diluted 1:50 with 25 mM MES buffer in M9 minimal medium, pH 6.0. 100 μl bacterial suspension was added to microtiter plate wells containing 100 μl of pig serum spiked with different tetracyclines." Example 4 (page 18, second paragraph), like that of Example 3, teaches the use of *E. coli* K-12/pTetLux1 in detecting the presence of tetracyclines in milk to which has been added EDTA. The specification does not teach how one of skill should proceed in the testing of samples such as "fish, meat, infant formula, eggs, honey, vegetables, serum, plasma, whole blood or the like" (claim 10).

At best Examples 3 and 4 address the aspect of using pig serum and milk as a starting material. Upon closer inspection, however, not even these two examples are found to provide the reactions conditions used for each of the assays. Accordingly, one of skill in the art would be forced to develop and identify reproducible conditions whereby such methods can be practiced. To force the public into enabling the practice of a method is an improper shift of the burden of enablement away from that of applicant to the public as it is the application, not the public,

which is to fully enable each and every claim. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.</u> This specification provides only a starting point, a direction for further research. (Emphasis added)

<u>The Nature of the Invention</u>

The claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The State of the Prior Art

The state of the art is limited in the area of recombinant mechanisms for the detection of tetracyclines.

The Relative Skill of Those in the Art

The relative skill of those in the art that is most closely associated with the claimed invention is high, on par with those that hold a Ph.D. in biochemistry.

The Breadth of Scope of the Claims

The claims have sufficient breadth of scope so to encompass any number of constructs that can be used in the detection of any level of tetracycline. As presently worded, the claimed method places no limitation on (a) the type of media used for culturing the transformant; (b) the type of transformant used; (c) the heterogeneity of the sample; (d) what means are used to determine just which tetracycline is present; (e) what means, if any, are employed so to determine the quantity of each tetracycline present; and (f) the level of sensitivity of the assay.

In view of the breadth of scope of the claims now before the Office, the unpredictableness of the assay system, and the limited guidance provided, the level of effort that needs to be exerted by the public in order to practice the full scope of the claimed method constitutes undue experimentation. Accordingly, applicant is again urged to consider adopting claims that more closely align the scope of the claims with the level of disclosure provided.

Response to argument

6. The request for filing an RCE in the subject application contained a request for entry of the amendment of 28 December 2001, Paper No. 13. The Advisory action of 10 January 2002 addressed the arguments provided in Paper 13 except for the aspect of Applicant's declaration, which is considered presently.

7. On 28 December 2001 a Declaration was filed under 37 CFR 1.132 by one Matti Karp, admitted co-inventor of the subject application. It is noted, therefore, that the remarks of declarant are not that of a disinterested third party but rather, one who holds an interest in the proceedings now before the Office. Declarant6 states that "[t]echniques for analyzing samples of biological tissues and fluids were well known at the time of the present invention," as were "[t]echniques for preparing recombinant DNA vectors and transformed host cells." Attention is directed to several publications, which are alleged to support this conclusion. Argument is also presented that the 'specification provides sufficient guidance to a person of ordinary skill in the art to practice the claimed invention;" attention being directed to page 9, lines 7-17.

8. Declarant's arguments have been fully considered and have not been found persuasive for while certain aspects of the technology may be known, the declaration does not point to how one using the prior art would know how to modify the prior art teachings so to arrive at applicant's

12. Claims 4, 17, and 19 recite the limitation "the plasmid pTetLux1" in lines 1-2. There is insufficient antecedent basis for this limitation in the claims.

13. Claims 5 and 18 recite the limitation "the insect luciferase gene" in line 2. There is insufficient antecedent basis for this limitation in the claims.

14. Claim 6 recites the limitation "the plasmid pTetLuc1" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 7 recites the limitation "the sensitivity of the analysis" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

16. Regarding claim 7, the phrase "e.g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

17. Claim 8 recites the limitation "the sensitivity of the analysis" and "the tetracycline derivative" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

18. Claims 8 and 9 provides for the use of cells (claim 8) and X-ray or photographic film, a CCD camera, a liquid scintillation counter or a luminometer (claim 9), but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

19. Claims 8 and 9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

22. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
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